IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:18-CV-220-FL

ANNIE MCNEIL-WILLIAMS, Plaintiff, v. DEPUY ORTHOPAEDICS, INC., DEPUY SYNTHES PRODUCTS, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON CONSUMER COMPANIES, INC., SMITH & NEPHEW, INC., BIOMET INC., ZIMMER BIOMET, INC., ZIMMER BIOMET HOLDINGS, INC., ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC., and DOE DEFENDANTS 1-100, Defendants.	)	RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Annie McNeil-Williams opposes Defendant's motion for summary judgment. Defendant has not met their burden of showing no factual dispute, and Plaintiff has not had any opportunity for discovery on the issue of Pre-emption. Plaintiff opposes this motion, and subsequently moves for discovery pursuant to FRCP Rule 56(d), and attaches a FRCP Rule 56(d) affidavit that adequately provides discovery requests and reasons why discovery is necessary. With her cross-motion for discovery, Plaintiff also attaches Plaintiff's interrogatories and requests for production on the preemption, which Plaintiff will serve with the Court's permission. Plaintiff specifically requests discovery that is needed to uncover details about the Defendant's PMA and post-sale knowledge of risks associated with the Product, steps taken to discover risks, and the processes used to ensure that adequate warnings and warranties were provided for the Product.

Until Plaintiff is allowed limited discovery on the issue, Plaintiff opposes Defendant's motion for summary judgment and asserts that the motion must be dismissed or continued with a deferred ruling pursuant to FRCP Rule 56(d).

I. Summary of nature of case

Plaintiff underwent a total knee replacement surgery on or about April 25, 2013, and her doctor implanted Defendant Depuy's Rotating Platform P.F.C. Sigma Knee ("The Product" or RP P.F.C. Sigma Knee"). Following the knee replacement surgery, the knee product failed, causing Plaintiff pain and immobility, and required a revision surgery on April 13, 2015. Defendant moves for summary judgment based on the doctrine of federal preemption, without any opportunity for discovery on the issue.

The Product is a Class III medical device approved by the United States Food and Drug Administration ("FDA") pursuant to the Pre-Market Approval ("PMA") process, and then was subsequently approved with the PMA supplements due to minor design changes. Under *Reigel v. Medtronic*, 552 U.S. 312 (2008), state common law claims are preempted by the FDA in many situations. However, state common law claims are *not* preempted if the state law duties parallel the FDA duties on the manufacturer—rather than imposing additional duties. Here, Plaintiff's failure to warn claim based on North Carolina state law parallels the duties to warn imposed on manufacturers by the FDA.

Therefore, Plaintiff's claims, particularly Plaintiff's failure to warn claims, are not preempted as a matter of law and Plaintiff is entitled to the opportunity for discovery on the preemption issue in order for the Court to rule on Defendant's limited summary judgment motion.

II. Procedural Background

Pursuant to this Court's June 26, 2018 order regarding the planning and scheduling of the deadlines in this matter, the parties' counsel made a good faith attempt to confer and submit a joint discovery plan. Defendants' counsel notified Plaintiff's counsel that Defendants intended to file summary judgment motions based on preemption pursuant to the Supreme Court's decision in *Reigel* because the PFC Sigma Rotating Platform Knee was subject to the FDA's PMA process. October 12th Declaration of Margaret E. Cordner in Support of Plaintiff's Motion to Vacate Order Pursuant to Rule 60(b)(20) ("October 12th Cordner Decl.") at ¶ 2. *See also* Defendants' Separate Report and Plan filed on July 31, 2018, Dkt. No. 18, at p. 2. During the parties' communications, Defendants' counsel proposed bifurcating the discovery process by first engaging in discovery solely related to preemption, then to engage in discovery on all other issues if Defendants' summary judgment motions on preemption were denied. October 12th Cordner Decl. at ¶ 4. While Plaintiff agreed that preemption discovery was needed to respond adequately to the issue of preemption, Plaintiff's counsel disagreed with the presumed efficiency of bifurcating discovery because the discovery issues for liability and preemption overlap and proceeding in this manner would likely to lead to duplicative discovery. October 12th Cordner Decl. at ¶ 5; Plaintiff's Separate Report and Plan filed on August 3, 2018, Dkt. No. 21. The parties filed separate reports and proposed discovery plans due to this disagreement regarding bifurcation of discovery in this matter. October 12th Cordner Decl. at ¶ 6.

Plaintiff submitted her proposed discovery plan, which covers topics directly relevant to Defendants' summary judgment motion on preemption:

> The Device History Record for the Product; The Device Master Record for the Product; The Medical Device Report for Plaintiff; The Product literature; The explanted components of the Product (if available); The Package insert that accompanied the Product and labeling, packaging and instructions for the Product; Communications between Defendants and the United States Food

> and Drug Administration concerning the Product; research, studies, reports relied on for approval of the Product; the manufacturing, development, research and distribution and post-release monitoring of the Product; Communications, advertisements, training, warnings provided to Defendants and Plaintiff/Plaintiff's healthcare providers; Adverse events communicated between Defendants and the United States Food and Drug Administration following the United States Food and Drug; Administration approval of the PFC Sigma Rotating Platform Knee; Literature and sources relied on regarding the efficacy and safety of the PFC Sigma Rotating Platform Knee.

October 12th Cordner Decl. at ¶ 7; Plaintiff's Separate Report and Plan filed on August 3, 2018, Dkt. No. 21, page 3.

Defendants contended in their separate report and proposed discovery plan, however, that "the only discovery relevant to preemption is the [Plaintiff's] own medical records establishing the Product at issue and the regulatory filings establishing that the Product was subject to the PMA process. (Both of which can be presented by affidavit to a summary judgment motion.)." October 12th Cordner Decl. at ¶ 8; Defendants' Separate Report and Plan filed on July 31, 2018, Dkt. No. 18, at p. 3.

On August 30, 2018, this Court held a telephone conference with counsel for Plaintiff and Defendant. October 12th Cordner Decl. at ¶ 9. During this call, Defendants expressed an interest in doing separate preemption discovery and a summary judgment motion on the preemption issue. October 12th Cordner Decl. at ¶ 10. Plaintiff's counsel was asked why counsel did not wish to do preemption discovery separate and apart from general discovery, in anticipation of a summary judgment motion on the preemption issue. October 12th Cordner Decl. at ¶ 11. In responding to this question, Plaintiff expressed concerns with undergoing duplicative discovery by doing preemption discovery prior to general discovery. October 12th Cordner Decl. at ¶ 12. Plaintiff respectfully disagrees with the Court that Plaintiff's counsel represented that discovery on the

preemption issue was *not* needed. October 12th Cordner Decl. at ¶ 13. Plaintiff indicated only that Plaintiff did not wish to have preemption discovery occur before and separate from general discovery. *Id.*

On August 31, 2018, this Court issued a case management order staying discovery on the preemption issue because "Plaintiff did not indicate the need for any such discovery." August 31, 2018 Case Management Order, Dkt. No. 25. Plaintiff respectfully disagrees with the Court's interpretation of Plaintiff counsel's need for discovery. Plaintiff indicated that Plaintiff did not want to bifurcate preemption and general discovery, but never meant to imply that Plaintiff did not need preemption discovery.

Defendant filed their Motion for Summary Judgment on October 15, 2018. On the same day, Plaintiff filed their motion to vacate the order staying discovery, after conferring with Defense counsel regarding the motion for summary judgment. Defendant filed an opposition to Plaintiff's motion to vacate the order staying discovery on October 29, 2018.

III. Legal Argument

A. Summary Judgment Standard

The moving party has the initial responsibility of informing the court of the basis for the belief that summary judgment is warranted. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); *Pulliam Inv. Co. v. Cameo Properties,* 810 F.2d 1282, 1286 (4th Cir. 1987). Once a motion for summary judgment is made and supported, the non-moving party "may not rest upon the mere allegations or denials of [that] party's pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). *See also Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). The non-movant "must do more than simply show that there is some metaphysical doubt

as to the material facts." *Matsushita Electric Industrial Co. v. Zenith Record Corp.*, 475 U.S. 574, 586, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986). [**7]

B. Defendant has not met their burden of showing the absence of a genuine issue of fact

Defendant has not met their "high burden" of showing that Plaintiff's claims should be dismissed as a matter of law because no genuine factual dispute exists.

Defendants claim that performing discovery on the issue of preemption would pose undue burden on Defendants. However, Defendants are always burdened when they are sued—whether the case is ultimately dismissed, summary judgment granted, a settlement reached, or a trial proceeds. This is a consequence of our fair judicial system and the federal rules of civil procedure. In this case, and on deciding the issue of preemption with adequate discovery, Defendants will not face any special, greater burden.

Determining whether Plaintiff's claims indeed parallel FDA regulations will be a fact-specific inquiry. A Defendant moving for summary judgment bears the burden of showing the absence of any genuine issue of material fact that it is entitled to judgment as a matter of law. *Jamil v. White, 192 F. Supp. 2d 413, 2002 U.S. Dist. LEXIS 5196* citing *Barwick v. Celotex Corp.*, 736 F.2d 946, 958 (4th Cir. 1984). A Defendant will prevail on a motion for summary judgment and establish an affirmative defense when it has "credible evidence -- using any of the materials specified in Rule 56(c) -- that would entitle it to a directed verdict if not controverted at trial." *Brinkley v. Harbour Rec. Club*, 180 F.3d 598, 1999 U.S. App. LEXIS 13125, 79 Fair Empl. Prac. Cas. (BNA) 1855, 138 Lab. Cas. (CCH) P33,891, 76 Empl. Prac. Dec. (CCH) P46,081, 44 Fed. R. Serv. 3d (Callaghan) 724 citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 331, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986) (Brennan, J., dissenting). Only when the defendant produces such evidence supporting its affirmative defense, the burden of production shifts back to the plaintiff

who "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *White v. Rockingham Radiologists, Ltd.*, 820 F.2d 98, 101 (4th Cir. 1987) (quoting Fed. R. Civ. P. 56(e))." Judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

Here, Defendant has not met her burden with the evidence put forth, which included Medical Records indicating the product identification and a declaration of Kathy J. Brocato, who confirms the FDA pre-market approval process for the Product and supplemental approvals. In this affidavit, Brocato merely confirms that "labeling, manufacturing processes or specifications affecting the safety or effectiveness of the device must go through a supplemental PMA process." (Brocato Decl. at ¶ 38.) She assures that "thousands of pages of testing results, clinical data, product descriptions, process controls and validations, and investigation reports have been submitted to and reviewed by FDA regarding the RP Knee System." (Id. *at ¶ 39.)* Without an opportunity for interrogatory requests, document production and depositions of Ms. Brocato and other witnesses, the mere assurance that Defendant's Product was approved with the PMA process will not suffice. Declaring that Defendant submitted Product information and changes to the FDA cannot by itself prove what knowledge of risks the Manufacture had, what steps were taken to discover risks, and the processes used to ensure that adequate warnings and warranties were provided to the FDA, patients and physicians.

C. Summary Judgment should not be granted until Plaintiffs have the Option for Pre-Emption Discovery

FRCP Rule 56(d) Standard

FED. R. CIV. PROCE. 56(d) provides:

If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:

(1) Defer considering the motion or deny it;

(2) Allow time to obtain affidavits or declarations or to take discovery; or
(3) Issue any other appropriate order.

The November 12, 2018 Declaration of Margaret E. Cordner in Support of Plaintiff's Rule 56(d) Motion ("November 12th Cordner Decl."), setting forth the evidence and reasons that Plaintiff cannot present facts essential to justify her opposition, is filed contemporaneously with this Rule 56(d) Motion. This Declaration provides, and is not limited to, the following:

- Discovery has been stayed, including discovery on the preemption issue, therefore Plaintiff has not served discovery requests, neither on liability nor preemption. ¶4
- Preemption discovery is necessary in order to oppose Defendant's motion for summary judgment. ¶8
- A PMA product is not automatically preempted because of duty to warn and warranty under North Carolina law. ¶9
- North Carolina law's duty to warn and warranty parallels, and does not exceed, the requirements imposed on a manufacturer by the FDA. ¶10
- Plaintiff requires information from Defendants that could be used to challenge the integrity of the Product's PMA and subsequent supplemental approval of The Product, particularly in regard to warnings, risks and warranties from the Manufacturer. ¶11
- Statements made about warnings for The Product, including warning labels, adverse events, instructions for use, or other written materials meant for consumers about The Product. ¶12(h)
- Identify sales and marketing data for The Product from 2000 to the present, as it relates to whether Defendant violated FDA regulations relating to distribution and adverse event reporting on The Product. ¶ 12(i)

- Identification of statistical analysis completed for The Product as it relates to complaints and adverse events. ¶12 (k)
- Documents relating to when Defendant advised the FDA and public of known risks and/or defects for The Product. ¶13(b)
- The Device History Record for the Product, as it relates to any changes to the Product and the reasons for those changes. ¶ 13(c)

November 12, 2018 Declaration of Margaret E. Cordner ("November 12th Cordner Decl.") attacjed as Exhibit A.

The Fourth Circuit has explained that the Court should not rule on a motion for summary judgment before the close of discovery on the facts at issue in the motion pursuant to Rule 56(f) [Now known as Rule 56(d)] Rule 56(f) [Rule 56(d)] specifically requires that "summary judgment be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition." *Ingle v. Yelton*, 439 F.3d 191, 194 (4th Cir. 2006), citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 n.5, 10 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)).

Ordinarily summary judgment is inappropriate "where the parties have not had an opportunity for reasonable discovery." *E. I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d at 448. To raise adequately the issue that discovery is needed prior to summary judgment, the nonmovant typically must file an affidavit or declaration pursuant to Rule 56(d) (formerly Rule 56(f)), explaining why, "for specified reasons, [**17] it cannot present facts essential to justify its opposition" without needed discovery. Fed. R. Civ. P. 56(d); *see Harrods*, 302 F.3d at 244-45 (discussing affidavit requirement of former Rule 56(f)).

In *McCray v. Maryland Dep't of Transp.*, 741 F.3d 480, 483 (4th Cir. 2014), the Fourth Circuit determined that the district court abused its discretion in dismissing an action before the

plaintiff had an opportunity to conduct discovery in connection with a Rule 56(d) motion. Id. at 483. The *McCray* Court noted: "summary judgment before discovery forces the non-moving party into a fencing match without a sword or mask." The Court reasoned, id. at 484 (internal citations omitted) (emphasis added):

> Non-movants must generally file an affidavit or declaration before they can succeed on a 56(d) motion, or if not, non-movants must put the district court on notice as to which specific facts are yet to be discovered. In this case, McCray filed such a declaration and identified the material she needed to discover.... **[*491]** *Similarly, nonmovants do not qualify for Rule 56(d)protection where they had the opportunity to discover evidence but chose not to*. There is no indication that McCray's inability to gather evidence was due to her own delay. In sum, . . . McCray's 56(d) motion should be granted.

See also Harrods, 302 F.3d at 246 (noting that nonmovant was entitled to 56(d) protection in part because it "was not dilatory in pursuing discovery").

In addition to Plaintiff's 56(d) affidavit, Plaintiff is attaching interrogatories attached as Exhibit B and requests for production of documents attached as Exhibit C.

D. Federal Preemption Does Not Bar Plaintiff's Complaint In its Entirety

In the *Riegel* decision, the Supreme Court established a two-step inquiry to decide when a Plaintiff's state common law requirements were different from, or in addition to, federal ones and would therefore by preempted. First, the inquiry asks whether the FDA established requirements applicable to the device. Second, the inquiry asks whether the Plaintiff's common-law state law claims are based upon state requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness. 21 U.S.C. 360k(a) has ruled that the United States Supreme Court's Medical Device Amendments of 1976 (MDA) does not preempt a state-law claim for violating a state-law duty that parallels a federal law duty under the MDA. A state can provide a damages remedy for claims premised on a violation of Food and

Drug Administration regulations; the state duties in such a case parallel, rather than add to, federal requirements.

Several federal duties are imposed on the Manufacturer by the FDA, including the duty to provide the FDA with "Adverse Reaction" and "Device Defect reports" and the duty under the "Medical Device Reporting regulation to report to the FDA whenever [manufacturers] receive or otherwise become aware of information…that reasonable suggest that a device marketed by the manufacturer…[m]ay have caused or contributed to a death or serious injury." *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733 (D. MD. Aug. 18, 2015). In *Williams*, the Court found that plaintiff's state law- Maryland – tort failure to warn claim was parallel to the federal requirements and thus was not preempted. Id. at 752-43. Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make "reasonable efforts" to convey an effective warning. And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Id at 742.*

Similarly, under North Carolina law, the federal duties are parallel to North Carolina state law duty on manufacturers to warn and warranty. In North Carolina, the duty to warn extends beyond the time of sale and requires the manufacturer to make reasonable efforts to continue to convey an effective warning and warranties.

In North Carolina, "a manufacturer of a product is under a duty to the ultimate purchaser, irrespective of contract, to use reasonable care in the manufacture and inspection of the article so as not to subject the purchaser to injury from a latent defect." *Goodman v. Wenco Foods, Inc.*, 333 N.C. 1, 26, 1992 N.C. LEXIS 671, *51, 423 S.E.2d 444 (1992). A defendant is liable for personal injuries resulting from use of a product that when it left the manufacturer's plant "was negligent in

its design of the product, in its selection of materials, in its assembly process, or in inspection of the product." *Id.*

In North Carolina, a manufacturer has a duty to make a product carefully where its nature is such that it is reasonably certain to place life and limb in peril where negligently made. *Corprew v. Geigy Chemical Co.*, 271 N.C. 485, 492, 157 S.E.2d 98, 103 (1967). A manufacturer is under a duty to inform itself about the safety designs and methods available in the industry at the time it designs or manufactures a product. *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 156, 385 S.E.2d 173, 175 (1989). A manufacturer must make reasonable tests to discover any latent hazards of its product. *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 157, 385 S.E.2d 173, 175-76 (1989). The manufacturer of a product must provide adequate safety devices on its products. *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 157, 385 S.E.2d 173, 176 (1989).

A manufacturer must properly inform users of a product's hazards, uses, and misuses, or be liable for injuries resulting therefrom under some circumstances. *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 156 (1989), citing *Milikan v. Guilford Mills, Inc.*, 70 N.C. App. 705, 320 S.E.2d 909 (1984), *cert. denied*, 312 N.C. 798, 325 S.E.2d 631 (1985). If a product is inherently dangerous due to its design, then the manufacturer must provide an adequate warning that, at the very least, contains safety precautions that are "reasonably commensurate with the dangers involved." *Smith v. Selco Products, Inc.*, 96 N.C. App. 151, 157 (1989), citing *Corprew v. Geigy Chemical Co.*, 271 N.C. 485, 157 S.E.2d 98 (1967).

Further, North Carolina recognizes that a manufacturer has a continuing post-sale duty to warn consumers of dangerous defects that it later discovers. *Mills v. GMC*, No. 96-2359, 1997 U.S. App. LEXIS 18839, *6 (4th Cir. July 23, 1997), citing *Smith v. Selco Prods., Inc.*, 96 N.C. App. 151, 158, 385 S.E.2d 173, 176-77 (1989). *See also Sisk v. Abbott Labs.*, 1:11-cv-159 2012

U.S. Dist. LEXIS 112260, *15 (W.D.N.C. June 19, 2012). A manufacturer of a product is liable based for inadequate warning if: (1) the manufacturer acted unreasonably in failing to provide a warning; (2) the failure to provide an adequate warning was the proximate cause of the plaintiff's harm; and (3) the manufacturer knew or should have known that when the product left its control that without an adequate warning the product created an unreasonably dangerous condition that posed a substantial risk of harm to a reasonably foreseeable consumer ***or that the manufacturer became aware of the substantial risk of harm after the product left its control***. *Sisk v. Abbott Labs.*, 1:11-cv-159, 2012 U.S. Dist. LEXIS 112260, *15 (W.D.N.C. June 19, 2012).

A duty to warn arises when the supplier of a product knows or has reason to know that the product is, or can be, dangerous for the use for which it is supplied. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003), citing *Stegall v. Catawba Oil Co.*, 260 N.C. 459, 133 S.E.2d 138 (1963). A products liability plaintiff asserting a failure to warn claim must allege, and ultimately show, that the injury was caused by the defendant's failure to warn. N.C. Gen. Stat. § 99B-5; *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003).

A defendant's knowledge, or lack thereof, regarding the potential dangers of its product is relevant to the issues of duty and causation. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003). When considering a negligence claim based upon failure to warn, and specifically the element of causation, it is the decision process of Plaintiff, as opposed to the specific injury, that must be considered. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003). The relevancy and admissibility of a defendant's knowledge of potential dangers of its product ***is thus not limited to only the specific injuries suffered by the plaintiff***. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706-07 (W.D.N.C. 2003). Indeed, evidence related to other injuries associated with use of a defendant's product demonstrate a defendant's

knowledge of risks associated with the use of its product, the risk / benefit analysis undertaken by the defendant, and proximate cause or cause-in-fact. *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003). The "probative value on the issue of notice to Defendant, duty to warn, and causation" of evidence of the defendant's knowledge, or lack thereof, of the dangerous propensities of its product substantially outweighs the potential risk of prejudice to the defendant, such that this evidence is ***not just discoverable but admissible***. See *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 707 (W.D.N.C. 2003).

Other courts have held that Plaintiff's position here is justified. *See, e.g.*, *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733 (D. MD. Aug. 18, 2015). In *Williams*, the Court found that plaintiffs' state law – Maryland – tort failure to warn claim was parallel to the federal requirements and thus was not preempted. *Id.* at 742-43. The plaintiffs' state's tort law recognizes that a "duty to warn can undergird a negligence case in a product liability action." *Id.* at 742 (internal quotations and citations omitted). "Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make "reasonable efforts" to convey an effective warning. And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." *Id.* The Court found that "this claim is parallel to several federal duties imposed by the PMA including, for example, the duty to provide the FDA with "Adverse Reaction" and "Device Defect" reports" (*id.* at 742) and the manufacturer's duty under the "Medical Device Reporting Regulation to report to the FDA whenever [manufacturers] receive or otherwise become aware of information . . . that reasonably suggests that a device marketed by the manufacturer . . . [m]ay have caused or contributed to a death or serious injury." *Id.* at 742-43 (internal quotations and citations omitted). The *Williams*' court found that the plaintiff's failure to warn claim was not preempted by the FDA or by section 360k. *Id.* at 743.

The same is true in this matter: North Carolina imposes a duty on manufacturers to warn, and this duty to extends beyond the time of sale and requires the manufacturer to make reasonable efforts to convey an effective warning. *Mills v. GMC*, 1997 U.S. App. LEXIS 18839, *6 (4th Cir. July 23, 1997); *Sisk v. Abbott Labs.*, 2012 U.S. Dist. LEXIS 112260, *15, 2012 WL 3155586 (W.D.N.C. June 19, 2012). Plaintiff's failure to warn claim in the instant matter is thus parallel to several federal duties imposed by the PMA and is not preempted. *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733 (D. Md. Aug. 18, 2015); *see also Smith v. Selco Prods., Inc.*, 96 N.C. App. 151, 158, 385 S.E.2d 173, 176-77 (N.C. Ct. App. 1989).

The Fourth Circuit recognizes that North Carolina's failure to warn claims pursuant to N.C. Gen. Stat. Ann. § 99B-5(a) are not preempted. *See generally, Carlson v. Boston Sci. Corp.*, 856 F.3d 320 (4th Cir. 2017). A plaintiff may prevail on this failure-to-warn claim if the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product "posed a substantial risk of harm" without an adequate warning ***either at the time of or after leaving the manufacturer's control***. *Carlson v. Boston Sci. Corp.*, 856 F.3d 320, 324 (4th Cir. 2017) (emphasis added). Of course, proving such claims requires discovery. *Id.* at 324 (partial summary judgment for defendant was granted on failure to warn claim after ***depositions and discovery*** on all issues bearing on the case was conducted). Thus, Plaintiff respectfully submits that discovery on these issues is not only warranted, but necessary.

Moreover, to the extent that Defendants in this matter submit that they can "prove" that all of Plaintiff's claims are preempted by the submission of an affidavit and supporting documents with the forthcoming motion(s) for summary judgment, Plaintiff is entitled to receive that discovery before Defendants' motion(s) are filed. To the extent that this evidence will be submitted with an affidavit of an unknown witness, with unknown personal knowledge averring facts

unknown and undiscoverable to Plaintiff at this time, Plaintiff is severely – if not fatally – prejudiced by the disallowance of discovery on those issues as well as Plaintiff's inability to cross-examine the anticipated affiant. Plaintiff respectfully requests discovery on the preemption issue in anticipation of Defendant's summary judgment motion will not prejudice Defendants, and relief from the discovery stay is justified.

IV. Conclusion

Dismissal as a matter of law is not warranted here because Plaintiff has shown that she has claims that are not preempted in this jurisdiction because the North Carolina state law claims parallel federal duties to warn and to warranty. Plaintiff would be severely prejudiced if she is not given the opportunity to conduct discovery to determine whether Manufacturer Defendant's breached the state and federal duty to warn and warranty.

Dated: New York, New York
November 12, 2018

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